AD_____

GRANT NO: DAMD17-94-J-4305

TITLE: Decision Modeling of Psychological and Clinical Factors in Assessing Treatment Alternatives for Lobular Carcinoma In Situ

PRINCIPAL INVESTIGATOR(S): Theresa J. Jordon, Ph.D.

CONTRACTING ORGANIZATION: New York University
School of Education
New York, New York 10003

REPORT DATE: 31 Aug 95

TYPE OF REPORT: Annual

PREPARED FOR: Commander
U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 0704-0188

1. AGENCY USE ONLY (Leave blank)	2. REPORT DATE	3. REPORT TYPE AND DATES COVERED
	31 Aug 95	Annual, August 1, 1994 - July 31, 1995

4. TITLE AND SUBTITLE
Decision Modeling of Psychosocial and Clinical Factors in Assessing Treatment Alternatives for Lobular Carcinoma in Situ

5. FUNDING NUMBERS
DAMD17-94-J-4305

6. AUTHOR(S)
Theresa J. Jordan, Ph.D.

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)
New York University
School of Education
New York, New York 10003

8. PERFORMING ORGANIZATION REPORT NUMBER

9. SPONSORING/MONITORING AGENCY NAME(S) AND ADDRESS(ES)
U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

10. SPONSORING/MONITORING AGENCY REPORT NUMBER

11. SUPPLEMENTARY NOTES

12a. DISTRIBUTION/AVAILABILITY STATEMENT
Approved for public release; distribution unlimited

12b. DISTRIBUTION CODE

13. ABSTRACT *(Maximum 200 words)*

The present project was designed to develop formal decision models, using both existing databases as well as personal preferences expressed by women with breast disease, to develop computer-based tools to help physicians and their patients decide on the optimal course of medical action for women with Lobular carcinoma *in situ*. During the first year of this project, formal decision models were constructed to fit the LCIS decision problems. Markov chaining was found useful in developing fine-tuned models. In addition, several national, local and international databases were examined for use in the decision tools. At the end of year 1 of this project, several presentations have been made/accepted for imminent presentation, and one abstract has been accepted for publication. The conclusions arrived at during this year are that: Devising useful decision models for LCIS is certainly feasible, and will provide assistance in making the very difficult treatment decisions involved in this disease. Second, recommendations must be made to generate more satisfactory longitudinal databases for women with LCIS so that the probabilities of developing invasive cancers can be estimated with greater accuracy.

14. SUBJECT TERMS
Lobular Carcinoma in situ
Breast Cancer
Decision Modeling

15. NUMBER OF PAGES
22

16. PRICE CODE

17. SECURITY CLASSIFICATION OF REPORT	18. SECURITY CLASSIFICATION OF THIS PAGE	19. SECURITY CLASSIFICATION OF ABSTRACT	20. LIMITATION OF ABSTRACT
Unclassified	Unclassified	Unclassified	Unlimited

GENERAL INSTRUCTIONS FOR COMPLETING SF 298

The Report Documentation Page (RDP) is used in announcing and cataloging reports. It is important that this information be consistent with the rest of the report, particularly the cover and title page. Instructions for filling in each block of the form follow. It is important to ***stay within the lines*** to meet *optical scanning requirements*.

Block 1. Agency Use Only *(Leave blank)*.

Block 2. Report Date. Full publication date including day, month, and year, if available (e.g. 1 Jan 88). Must cite at least the year.

Block 3. Type of Report and Dates Covered. State whether report is interim, final, etc. If applicable, enter inclusive report dates (e.g. 10 Jun 87 - 30 Jun 88).

Block 4. Title and Subtitle. A title is taken from the part of the report that provides the most meaningful and complete information. When a report is prepared in more than one volume, repeat the primary title, add volume number, and include subtitle for the specific volume. On classified documents enter the title classification in parentheses.

Block 5. Funding Numbers. To include contract and grant numbers; may include program element number(s), project number(s), task number(s), and work unit number(s). Use the following labels:

C	- Contract	PR	- Project
G	- Grant	TA	- Task
PE	- Program Element	WU	- Work Unit Accession No.

Block 6. Author(s). Name(s) of person(s) responsible for writing the report, performing the research, or credited with the content of the report. If editor or compiler, this should follow the name(s).

Block 7. Performing Organization Name(s) and Address(es). Self-explanatory.

Block 8. Performing Organization Report Number. Enter the unique alphanumeric report number(s) assigned by the organization performing the report.

Block 9. Sponsoring/Monitoring Agency Name(s) and Address(es). Self-explanatory.

Block 10. Sponsoring/Monitoring Agency Report Number. *(If known)*

Block 11. Supplementary Notes. Enter information not included elsewhere such as: Prepared in cooperation with...; Trans. of...; To be published in.... When a report is revised, include a statement whether the new report supersedes or supplements the older report.

Block 12a. Distribution/Availability Statement. Denotes public availability or limitations. Cite any availability to the public. Enter additional limitations or special markings in all capitals (e.g. NOFORN, REL, ITAR).

DOD	- See DoDD 5230.24, "Distribution Statements on Technical Documents."
DOE	- See authorities.
NASA	- See Handbook NHB 2200.2.
NTIS	- Leave blank.

Block 12b. Distribution Code.

DOD	- Leave blank.
DOE	- Enter DOE distribution categories from the Standard Distribution for Unclassified Scientific and Technical Reports.
NASA	- Leave blank.
NTIS	- Leave blank.

Block 13. Abstract. Include a brief *(Maximum 200 words)* factual summary of the most significant information contained in the report.

Block 14. Subject Terms. Keywords or phrases identifying major subjects in the report.

Block 15. Number of Pages. Enter the total number of peges.

Block 16. Price Code. Enter appropriate price code *(NTIS only)*.

Blocks 17. - 19. Security Classifications. Self-explanatory. Enter U.S. Security Classification in accordance with U.S. Security Regulations (i.e., UNCLASSIFIED). If form contains classified information, stamp classification on the top and bottom of the page.

Block 20. Limitation of Abstract. This block must be completed to assign a limitation to the abstract. Enter either UL (unlimited) or SAR (same as report). An entry in this block is necessary if the abstract is to be limited. If blank, the abstract is assumed to be unlimited.

*U.S.GPO:1993-0-358-779

FOREWORD

Opinions, interpretations, conclusions and recommendations are those of the author and are not necessarily endorsed by the US Army.

____ Where copyrighted material is quoted, permission has been obtained to use such material.

____ Where material from documents designated for limited distribution is quoted, permission has been obtained to use the material.

____ Citations of commercial organizations and trade names in this report do not constitute an official Department of Army endorsement or approval of the products or services of these organizations.

____ In conducting research using animals, the investigator(s) adhered to the "Guide for the Care and Use of Laboratory Animals," prepared by the Committee on Care and Use of Laboratory Animals of the Institute of Laboratory Resources, National Research Council (NIH Publication No. 86-23, Revised 1985).

____ For the protection of human subjects, the investigator(s) adhered to policies of applicable Federal Law 45 CFR 46.

____ In conducting research utilizing recombinant DNA technology, the investigator(s) adhered to current guidelines promulgated by the National Institutes of Health.

____ In the conduct of research utilizing recombinant DNA, the investigator(s) adhered to the NIH Guidelines for Research Involving Recombinant DNA Molecules.

____ In the conduct of research involving hazardous organisms, the investigator(s) adhered to the CDC-NIH Guide for Biosafety in Microbiological and Biomedical Laboratories.

Accesion For	
NTIS CRA&I	☑
DTIC TAB	☐
Unannounced	☐
Justification	
By	
Distribution /	
Availability Codes	
Dist	Avail and / or Special
A-1	

PI - Signature Date 8/31/95

TABLE OF CONTENTS

DECISION MODELLING OF PSYCHOLOGICAL AND CLINICAL FACTORS IN ASSESSING TREATMENT ALTERNATIVES FOR LOBULAR CARCINOMA IN SITU

INTRODUCTION

Since the 1940's, lobular carcinoma *in situ* (LCIS) has been recognized as a breast finding requiring either aggressive treatment or intensive follow-up. LCIS is a finding in the breast tissue which does not fit into treatment protocols for other types of breast cancer because it is actually a benign finding insofar as it is not an invasive, life-threatening disease.

Stated simply, LCIS poses a medical and personal dilemma: in itself, it is a benign finding. However, LCIS appears to serve as a marker of increased risk for subsequent development of malignant breast lesions. It has been suggested that this increased risk may be as high as ten-fold. On the other hand, good statistics regarding risk over time in women with LCIS are difficult to find: few longitudinal studies exist; and those that do, began before the advent of low-dose mammography, which relegated most women with LCIS to treatment with preventive bilateral mastectomy. Consequently, even longitudinal data provide relatively inadequate comparison women, i.e., largely those women who refused treatment on the basis of a broad range of personal considerations.

The dilemma of what to do medically with an LCIS patient is heightened by the fact that LCIS appears to occur most frequently in premenopausal women. Failure to remove the risk of invasive breast cancer for young women may deprive them of longer life expectancies than failure to perform preventive mastectomies on older patients. On the other hand, the importance a woman

places on retaining her breasts may or may not vary with age. While the "conventional wisdom" may be that younger women are more reluctant to undergo preventive bilateral mastectomies than older women, our work with women from their thirties onward suggests that the decision varies greatly from woman to woman, and may correlate little with age. Consequently, in making the decision to perform surgery or not, both the individual woman's preferences as well as her normal life expectancy must be taken into account.

Finally, LCIS is a difficult diagnosis to make: it is not readily palpable on physical examination, and lacks clear mammographic signs. Consequently, it is most frequently discovered "by accident" when breast tissue is biopsied for another purpose. Findings on mammography are frequently not detected until LCIS has become invasive breast cancer.

As in the treatment of many diseases, the pendulum has swung back and forth on the issue of LCIS. Initially, in the 1940's, preventive bilateral mastectomy provided the only treatment option. With the advent of low-dose mammography in the mid-1970's, a "watch and wait" approach appeared to be a possible alternative: image the breasts on a frequent basis, perhaps every several months, in the anticipation that a malignancy would be detected in time to achieve a cure. On the other hand, frequent irradiation to the breast, particularly in younger women, posed its own concerns: iatrogenic breast cancer, i.e., cancer caused by too much radiation. Furthermore, some women elect surgery rather than suffer the psychological discomfort of living with the threat of possible terminal disease.

There is no single, clear answer to the dilemma of LCIS that has emerged from the literature to date. However, mathematical models of disease processes and the data to support decision models have recently become available. Consequently, the purpose of the present

investigation was **to develop formal decision models, utilizing both existing data bases as well as personal preferences (values) expressed by women with breast disease, to develop tools that will help physicians and their patients decide on the optimal course of medical action when confronted with LCIS.**

BODY

Two major tasks comprised the first year's work on this project:

1.) Developing a series of decision models that could be used as optimal tools for the LCIS decision; and

2.) Assessment of the usefulness of existing databases for incorporation into the formal decision processes.

While the inclusion of complex personal values will comprise one of the major foci of year 2 of this project, we have made progress in beginning to assess personal values regarding treatment of LCIS. This "values" aspect, plus refinement of the decision tool with a user-friendly interface, will comprise the large part of the work during 1995-96.

The Decision Models

Figure 1 shows an example of one of the basic decision models developed and evaluated for use in this project. As you will note, static time frames of fifteen and twenty years are shown in the branches of the decision tree. While static time frames are inferior to frequent Markov chaining, it remains unclear as to whether existing data will permit a finer tuning of the decision process at this point.

For ease of use of existing databases as well as theories regarding the lag time involved in the

development of breast malignancy, this first decision tree presents an extremely general view of the problem. Existing literature suggests that if a woman with LCIS does not undergo preventive mastectomy and develops invasive breast cancer, this will occur within approximately fifteen years. If her cancer is "caught" in time to achieve a cure, and if she survives surgery, she will be assigned a normal life expectancy. On the other hand, if her cancer is too advanced to achieve a cure, she is assigned an additional five years of life. Women who undergo preventive surgery "now" are assigned a normal life expectancy if they survive surgery with or without reconstruction, and are assigned a zero life expectancy if they suffer surgical mortality.

Obviously, this fifteen, twenty, normal life expectancy, and immediate surgical mortality oversimplifies the true dilemma of LCIS, and also masks answers to some of the critical questions that may be raised about treatment, such as : **If I am a 40 year old women with a finding of LCIS, is there an "optimal" time at which I should have surgery? That is, can I afford to wait another ten years, or another fifteen years, for example, before having surgery?**

There are two issues that assist in answering this kind of question, at this point in contemporary medicine. First, Markov chaining added to the decision model is capable of producing a computerized tool that will assess a woman's estimated risk on a year by year (or even month by month) basis. Not only does the capability for Markov chaining exist, but some of what is known about LCIS assists in the Markov model: while the data regarding LCIS is rather disappointing, what has become somewhat apparent is that the incidence of a women with LCIS developing invasive breast cancer seems to be approximately equal each year. That is, there is no reason, given existing literature, to assume that her risk of malignancy is greatest in the first five years after her LCIS diagnosis, or in the next ten years, etc. This may be due to the fact that, as

mentioned earlier, LCIS is usually an accidental diagnosis. Add to this the fact that, on autopsy, many women are found to have LCIS without any evidence of malignancy during their lifetimes. Consequently, it is possible to extrapolate from the data that do exist to develop models that will inform women and their physicians about the point in time at which the woman's risk for malignancy exceeds what she is willing to accept.

Figure 2 shows the basic decision model adjusted for Markov chaining. While it is not possible to illustrate easily the cycling that occurs in a Markov process, some fundamental changes in the decision model are clear: at the point at which Markov processing begins, there is no longer an indication of a static 15 year or 20 year life expectancy for those who do not undergo surgery. The reason for this change is that the woman's risk for malignancy is examined each year. At each year, the process will assess her likelihood of having developed malignancy, the likelihood that the malignancy is caught early enough to achieve a surgical cure, the likelihood that she will suffer surgical mortality, as well as the likelihood that she has remained cancer-free. If she has died during surgery in year one, she exits the Markov process. If she has survived cancer-free, she reenters the process in year two with the same risk of malignancy she faced during year one. If she remains cancer-free, she reenters the model for year three. If not, she cycles through the cancer options as per above. (This process can be fine-tuned even further if we decide to Markov the life expectancy of women with terminal cancers, fitting these to survival curves based on incidences of catching cancers at varying stages of invasiveness.)

A final note regarding decision modelling in this project: During the course of 1994-95, we began our modelling with existing decision software, which was useful but relatively weak in wedding Markov chains to complex models as well as using decision models to explore the use of

other mathematical models such as Path models. During the middle of the year, a new program named *DataEase* emerged on the market which enabled us to fine-tune our models to a greater degree, and to explore even beyond the models we had initially conceptualized. This was a boon to our work on modelling.

Assessment of Existing Data

One of the crucial factors that has entered into our work during the past year is the finding that our capability to build good models exceeds the quality of the data that presently exist regarding LCIS.

A thorough search of the U.S. SEER database for cases of LCIS was of little use. A small sample of cases was recovered, but little useful information was provided regarding the cases, e.g., geographical location, hospital or clinic type, etc. This was not surprising since the focus of SEER had been to provide a national view of all types of cancers, rather than to study in depth any particular malignancy. Consequently, no data were obtained regarding cases of LCIS which showed later as malignancies, or lag times between LCIS diagnoses and malignancies. Tracking individuals in the SEER database was particularly difficult for a number of reasons, including the fact that reentry of women into the database, as when a woman with LCIS presented later with breast cancer, was treated as a new case. No attempt appears to have been made to cross-check cases; and in instances in which names were changed due to marriage or divorce, there is no possible way to match cases.

Data from Sweden provide a clearer picture of the incidence of breast cancers and other breast diseases by age of woman and causes of deaths. These data are helpful in that a clearer view of the incidence of breast diseases and breast cancer mortalities by age group can be obtained from

Sweden's socialized medicine sources than is possible through the two major resources available in the U.S.which suffer from volunteer samples as well as other flaws: HIP (Health Insurance Plan study) and BCDDP(Breast Cancer Detection and Demonstration Project). On the other hand, the Swedish data from which we presently are working are from the Statistisk Arsbok published by *Statistiska Centralbyran*. These data are presented in useful, tabular form, but do not provide essential longitudinal follow-up data. Consequently, it is impossible to track a case from LCIS to death from breast cancer. An example of an entry in the Statistisk Arsbok is as follows:

CAUSE OF DEATH	TOTAL	AGE OF WOMAN				
		15-44	45-54	55-64	65-74	75-
MALIGN TUMOR						
I BROSTKORTEL	1577	117	184	273	418	585

While such data, reflecting a population rather than volunteer samples, provide more reliable information regarding morbidity and mortality, they fall short of longitudinal data, and do not necessarily reflect the incidences and prevalences in the U.S. It is possible that further work through the American Scandinavian Foundation will enable us to find out and use, if possible, any existing Swedish longitudinal information.

One of the best data resources that appears to exist for our modelling is the longitudinal database on LCIS women compiled by the Connecticut Department of Health beginning in the 1940's. These data provide the best information we have regarding the connection between LCIS and malignancy, as well as incidence curves. However, two problems exist. First, the database was begun prior to the advent of low-dose mammography, so that most women in the database

prior to the mid-1970's received treatment with preventive bilateral mastectomy. Data obtained later, when the "watch and wait" approach began to gain some acceptance, do not comprise large comparison groups. On the other hand, this database serves as a model for what should be done to track LCIS: not only is the date of the finding of LCIS important, including the age of the patient at diagnosis, but also the length of follow-up including the stage of malignancy when an invasive cancer has occurred. These are the data upon which we are presently attempting to build our most accurate models. **It must, however, be cautioned that the Connecticut database was developed for a specific reason: the incidence of LCIS in Connecticut had been alarming, thereby initiating the development of a longitudinal database. It is likely that this database may not reflect other segments of the U.S. population. However, it can serve as a prototype for other LCIS databases which are desperately needed in this country.**

CONCLUSIONS

The Body of Work discussed above addresses many of the conclusions that have been reached during the first year's work on this project. To summarize what we have done and what we have learned thus far, we offer the following points:

1. It appears that decision modelling with Markov chaining provides a good approach to enable physicians and patients to arrive at optimal decisions regarding the treatment of LCIS, decisions which can incorporate individual women's values as well as year by year risks and life expectancies if a "watch and wait" rather than a surgical approach is taken.

2. The present data on LCIS is somewhat disappointing. This was anticipated to some degree, since LCIS is typically discovered by "accident." On the other hand, it appears that data from a

number of sources, particularly the Connecticut Department of Health database, will enable us to provide prototype models that will provide preliminary answers to questions about LCIS treatment--and will also provide a "shell" which can be altered to reflect the particular risks that may in future be discovered to characterize subgroups of women with LCIS.

3. Obtaining personal values from women with and without breast disease does not pose a problem for our second year of work, since our working contacts for these data are firmly in place.

4. Building a user-friendly front end to the existing decision model will be done during this second year.

In conclusion, we anticipate that at the end of the project, we will have working models of the LCIS decision problem that will be usable by both patients and physicians. The data that comprise the probabilities in these models will be the weakest link. From our experience with existing databases, we will provide suggestions for LCIS databases that will be better able to provide the robust data desirable for making optimal treatment decisions in this medical dilemma.

BIBLIOGRAPHY

Symposium for Decision Theory Special Interest Group at the Eastern Educational Research Association Conference, March, 1995. (See attached symposium.)

T.J. Jordan, et al., Decision models for treatment of lobular carcinoma *in situ*. Abstract accepted for presentation and publication at the European Congress on Clinical Oncology. Invited by President of Organization, M. Rouesse. Paris, France, Oct.-Nov., 1995. (See attached abstract.)

PERSONNEL PAID FROM GRANT DURING 1994-95

Dr. Theresa J. Jordan, P.I.

Dr. Barbara Hummel-Rossi, Co-P.I.

Dr. Richard Montgomery, Special Consultant

APPENDICES

FIGURE 1. BASIC DECISION MODEL

FIGURE 2. DECISION MODEL WITH EXAMPLE OF MARKOV CHAINING

SYMPOSIUM ON BREAST CANCER AND DECISION MAKING

ABSTRACT FOR THE EUROPEAN CONGRESS ON CLINICAL ONCOLOGY

ABSTRACT SUBMITTED FOR THE MARCH, 1996 AMERICAN EDUCATIONAL RESEARCH ASSOCIATION

FIG. 1. BASIC DECISION MODEL FOR TREATMENT OF LCIS

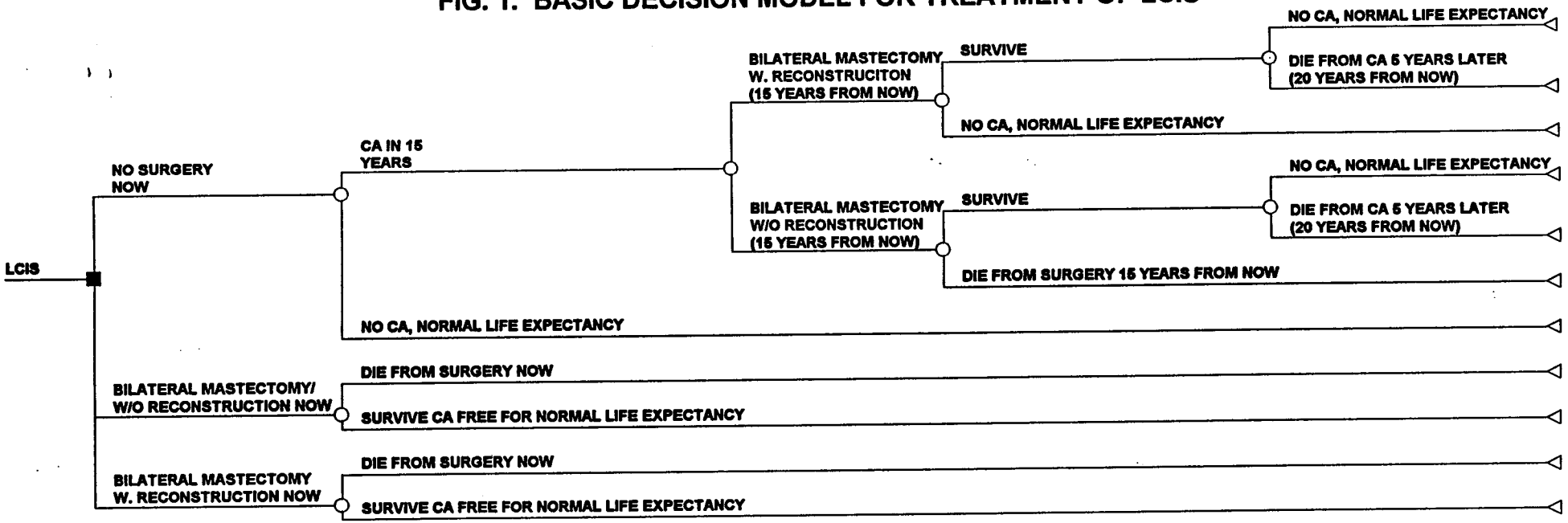
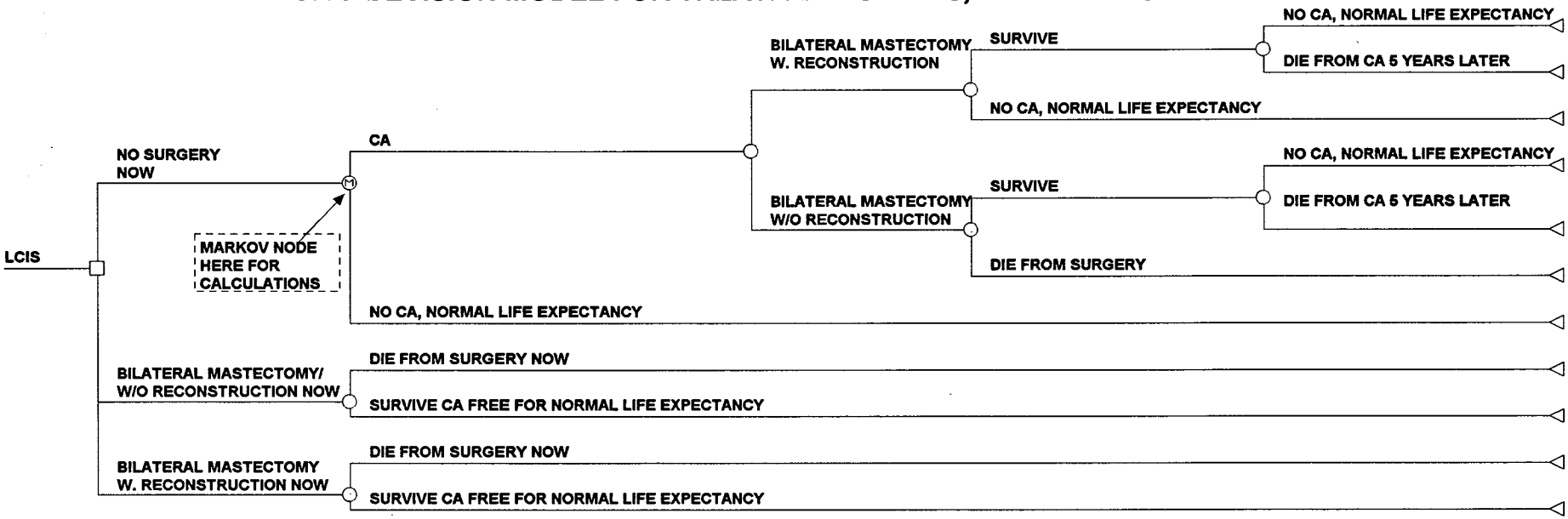


FIG. 2. DECISION MODEL FOR TREATMENT OF LCIS, WITH MARKOV NODE INDICATED



MARKOV NODES PERMIT CHAINED CALCULATIONS OVER FIXED INTERVALS. A ONE YEAR INTERVAL FOR RISK OF CA , AS WELL AS ITS CONSEQUENCES, CAN BE CYCLED FOR YEARS TO OBTAIN A DYNAMIC MODEL OF LCIS RISK OVER THE LIFETIME, PERHAPS 40 YEARS FOR A WOMAN PRESENTLY AGED 45 YEARS.

Symposium for Decision Theory Special Interest Group
Developed by Theresa J. Jordan, Ph.D.,
Dept. of Applied Psychology, N.Y.U.

Symposium Title: Impact of Culture, Ethnicity, and Personal History on Health Care Decisions for Breast Cancer

Chair: Theresa J. Jordan, New York University

International Perspectives on Breast Cancer Detection: Sweden v. the U.S.
Theresa J. Jordan, Applied Psychology, N.Y.U.

The Role of Epidemiology in Global Health Care Decisions
Richard Montgomery, New Jersey Dental School

Incorporating "at risk" Information into Treatment Decisions for Breast Cancer
Barbara Hummel-Rossi, Applied Psychology, N.Y.U.

Links between Breast Cancer Treatment Trends and Feminist Perspectives
Kristen Callahan and Glynnis Elliot-Scanlon,
Applied Psychology, N.Y.U.

Discussant: Mervin Lynch, Northeastern University

cs proposed for Proffered Papers sessions.

e tick one box which relates to the subject of the abstract.

: Science/Medicine

ids related malignancies
iological response modifiers
'adder cancer
MT and PSCT
'east cancer—adjuvant therapy
'east cancer—diagnostic and prognostic
ctors
'east cancer-local treatment
east cancer-treatment of advanced dise ase
inical pharmacology/Phase I studies
lorectal cancer
ug resistance
idemiology
ne therapy
owth factors
ad and neck tumours
dgkin's disease
lney cancer
ukemia and myeloma
ng cancer non-small cell
ng cancer small cell

- [ ] Melanomas
- [ ] Nervous system tumours in adults and children
- [ ] Non-Hodgkin's lymphoma
- [ ] Oncogenes and suppressor genes
- [ ] Other gastro-intestinal tumours
- [ ] Other gynaecological tumours
- [ ] Ovarian tumours
- [ ] Paediatric oncology
- [ ] Palliative treatment
- [ ] Pre-clinical drug development-new targets
- [ ] Prostate cancer
- [ ] Psychosocial oncology
- [ ] Radiobiology
- [ ] Radiotherapy
- [ ] Sarcomas
- [ ] Supportive care
- [ ] Surgical aspects
- [ ] Testicular tumours
- [ ] Tumour markers
- [ ] *Miscellaneous

ng

icer: a family experience
cer nursing: a European dimension
nging approaches in cancer clinical trials:
ursing contribution (posters only)
nplementary care: implications for
er nursing practice
mmunication in cancer care
lth promotion and cancer prevention
lity assurance in cancer care
abilitation
e of the art of cancer nursing practice

Method of presentation

Please tick your preferred method of presentation.

- [ ] oral
- [ ] poster
- [x] no preference

Keywords

Proposed keywords for indexing (maximum 3 keywords).

CARCINOMA IN SITU,
DECISION ANALYSIS

ABSTRACT FORM

To return to the ECCO 8 secretariat before 15 March 1995

(Office use)

TOP

DECISION MODELS FOR TREATMENT OF *LOBULAR CARCINOMA IN SITU*

TJ Jordan[1], RL Montgomery[2], RL De Jager[3]
[1]New York University, NY, USA; [2]University of Medicine and Dentistry of New Jersey, NJ, USA; [3]Perlmmune, Inc, Rockville, MD, USA

Since its identification in the 1940's, *Lobular Carcinoma in situ* has posed a treatment dilemma: Whether to "watch and wait" until the benign lesion becomes malignant, or to perform preventive bilateral mastectomy. This lesion occurs most frequently in premenopausal women, and may remain benign for the remainder of the lifespan. Furthermore, with the advent of low radiation dosage mammography in the 1970's, there is some evidence to suggest that frequent mammographic screening, *i.e.*, at least twice per year, is preferable to preventive mastectomy. The major issue addressed in this investigation is whether frequent screening is, in fact, the preferred alternative when risks of malignancy, patient age, premature deaths, excessive radiation exposure, and compliance with a strict screening regimen are taken into account. The decision models developed in this investigation incorporate these factors; utilize risk estimates obtained from several longitudinal databases' and incorporate three methods for assigning utility values to the outcomes of each course of action. Results of decision analyses suggest that preventive bilateral mastectomy may be the treatment of choice in women younger than 50 years, and that screening may be preferable for women aged 75 and older. The most equivocal findings are for middle aged women in their fifties: It is this group for whom quality of life issues play the most significant role in determining optimal course of medical action, because it is at this point in life that life expectancies do not clearly outweigh subjective values.

Guidelines

The original abstract will be used as a master for camera-ready printing. It is essential that all the abstract conforms to the guidelines. Abstracts that do not conform to the guidelines will be rejected. See page 18 for details.

Sponsorship

Abstracts must be sponsered by a member of ESMO, ESSO, ESTRO, EACR, EONS or SIOP (Europe). Please indicate the name of the sponsoring member and the corresponding society. See page 18 for details.

(name) ROUESSE (society) ESMO

Development of an Instrument to Measure Fear of Breast Cancer

Barbara Hummel-Rossi
53 Cherry Lane
Huntington, NY 11743

Barbara Hummel-Rossi
New York University

Theresa J. Jordan
New York University

Objective

While it might appear obvious that reports of increased incidence of breast cancer would encourage women to engage in a screening program including mammography, this is not necessarily true. Such reports are frightening and the medical literature on compliance informs us that fear often encourages individuals to avoid rather than comply with diagnostic and treatment regimens (Kerlikowski, Grady, Rudin, Sandrok & Ernster, 1995). Informal discussions with women affiliated with breast cancer action coalition groups confirm that many women are so frightened of breast cancer that they are avoiding screening. The media have touted breast cancer as so prevalent as to be virtually unavoidable that many women believe that no prevention activities on their part will make a difference. By not screening for breast cancer, these women believe that they are delaying the inevitable. We need to understand the dimensions of this fear of breast cancer so that we can design better educational programs to teach about the realities of breast cancer. It was, therefore, the purpose of this study to design an instrument to measure fear of breast cancer.

Perspective

The national Center for Disease Control (CDC) has reported that 1 in 9 women will develop breast cancer during their lifetimes. Previous releases had set the odds at 1 in 11. In some geographic areas, such as Long Island, New York, the risk appears to be much higher, although it is unclear whether this is a "real" risk or an artifact of more women complying with a screening regime.

There are numerous problems with the data from which breast cancer risk estimates are derived in the United States. For example, what appeared to the general public to be an increase in risk of breast cancer (from 1 in 11 to 1 in 9) was actually the result of the CDC deciding to include cancer rates of women in their 80's and older, previously excluded from analysis, in their calculations (National Cancer Institute Breast Cancer Screening Consortium, 1990). The only factor that changed was how the epidemiologists defined their population. Considering that everyone dies from something, it is not surprising that when older women were included in the calculations the risk of breast cancer "increased." A second glaring problem is the fact that 1 in 9 is often misinterpreted to mean that "right now, my chances of having breast cancer are 1 in 9." This interpretation is false. A correct interpretation is, "If the currently reported statistics are correct, the chances that I will develop breast cancer over the course of my lifetime is 1 in 9." In fact, a woman has a much greater probability of dying from heart disease than she does of dying from breast cancer. Finally, the data base from which the US risk

estimates are calculated is nonrepresentative of the geographic regions in this country and has gross recording errors.

Given this misinterpretation of poor data, a scare media campaign, and the fact that breast cancer entails the possibility of surgery, chemotherapy and/or radiation, and possible disfiguring body changes, is it any wonder that many women are afraid of breast cancer? If we are to design successful breast cancer screening educational programs, we must first understand the feelings that women experience and then design programs which take into account these feelings. This research was designed to understand and measure one component of these feelings - the fear of breast cancer.

Method

Test Development. Structured interviews designed to elicit comments about breast cancer fears were conducted with three female directors of breast cancer action coalition groups from the New York City metropolitan area. These women are highly knowledgeable about all aspects of breast cancer, including the attitudinal component. In addition, three women over 45 years old from the same geographic area who had not had a mammogram in the past five years were interviewed and asked about their decision to not have a mammogram. Based on these interview results and a review of the breast cancer and screening compliance literature, fear of breast cancer and its five theorized dimensions were defined. Next, 10 items were developed to assess each of the five dimensions. The items were then written on 3 by 5 cards and placed in envelopes according to the dimension the item was designed to measure. The corresponding dimension definitions were written on the outside of the envelopes The items were submitted to the three directors of the breast cancer action coalition groups. They were asked to review the items to determine (1) if each item measured the construct it was designed to measure, and (2) if wording and content were appropriate. One of the coinvestigators sat with each director as she reviewed the items and recorded the immediate verbal reactions to the items. Based on these responses the instrument was revised; items were eliminated, wording changed, and items added.

At this point, the first draft of the 40 item instrument was available. Demographic items were added; however, the instrument remained anonymous. The instrument was now pilot tested on 20 women ages 40 to 65 from the greater New York metropolitan area. The women were drawn from church groups and Parent Teacher Associations. The women were told that the instrument was under development and that their comments on items were welcome. After responding to the instrument each woman was briefly interviewed by one of the coinvestigators to determine if she had encountered any problems with the instrument. Based on these responses, the instrument was again revised. The second draft of the instrument with 35 items is currently being used in the validity studies.

Validity Studies. Construct and content validity are the most important forms of validity for this instrument. Content validity has been addressed through the test development procedures. Two studies are currently underway to check the construct validity. The instrument is being administered to 250 women between the ages of 40 and 65 from the greater New York City metropolitan area.. This sample is being drawn from the membership of the following groups: American Association of University Women,

several Parent Teachers Associations, NOW Task Force of Women of Color, and African American Women in Health.

Using the SPSS statistical program, factor analyses will be conducted to identify the factors in the test. If the factors identified through the factor analyses represent the theoretical dimensions of fear of breast cancer to which the test was written, this will be considered evidence in support of the construct validity of the instrument.

After responding to the instrument, twenty-five of the sample of 250 women are being interviewed through a structured interview. The interview contains open-ended questions designed to elicit degree of fear of breast cancer. Concordance between instrument response and interview response will be considered evidence in support of the construct validity.

Reliability Study. Reliability will be investigated through application of Cronbach's coefficient alpha to the data obtained from the 250 women.

It is anticipated that based on the validity and reliability studies and an item analysis further refinement of the instrument may be necessary.

Educational Importance

In a recent article on designing effective health promotion and disease prevention educational programs, Winett (1995) stressed the importance of knowing your target population and tailoring the education program to the population. This point needs to be applied to breast cancer screening educational programs. We know that many women have a great fear of breast cancer. We need to understand this fear and use this understanding to design better breast cancer screening educational programs. The recent genetic work identifying genes associated with breast cancer is medically encouraging; however, the alternatives it could offer women with mutated genes could serve to make women even more fearful. Education of women will become an even more important issue.

References

Kerlikowski, K., Grady, D., Rubin, S. M., Sandrock, C., & Ernster, V. L. (1995). Efficacy of screening mammography: A meta-analysis. Journal of the American Medical Association., 273 (2), 149-53.

National Cancer Breast Screening Consortium, (1990). Screening mammography: A missed clinical opportunity? Results of the NCI Breast Cancer Screening Consortium & National Health Interview Survey Studies. Journal of the American Medical Association, 264 (1), 54-58.

Winett, R. A. (1995). A framework for health promotion and disease prevention programs. American Psychologist, 50, 341-350.